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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Inventor: Timothy A. M. Chuter

Patent No.: 6,814,752 B1

Serial No.: 09/780,943

Issued: November 9, 2004

Filed: February 9, 2001

For: MODULAR GRAFTING SYSTEM AND METHOD

Examiner: David J. Isabella

Group Art Unit: 3738

Docket No.: ENDOV-56584

January 5, 2005
Los Angeles, California

REQUEST FOR CERTIFICATE OF CORRECTION

Certificate of Corrections Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The above-identified patent has been found to have the errors set forth in the enclosed Certificate of Correction. It is requested that this Certificate of Correction be issued and returned to us. Since the errors occurred in the final printing phase of the patent, no fee is enclosed. However, should the Office determine that a fee is required, please charge our account no. 06-2425.

The errors are verifiable in the patent application file as follows:

ERROR	VERIFICATION
Column 1, line 26, delete "stentgraft" and insert --stent-graft--.	See page 1, line 18 of Background of the Invention.
Column 3, line 22, delete "filly-stented" and insert --fully-stented--.	See page 5, line 21 of Summary of the Invention.
Column 6, line 18, delete "Man" and insert --than.--.	See page 11, line 2 of Description of the Preferred Embodiments.
Column 8, line 23, delete "80,90" and insert --80, 90--.	See page 14, line 18 of Description of the Preferred Embodiments.
Column 11, line 24, delete "365,366" and insert --365, 366--.	See page 19, line 21 of Description of the Preferred Embodiments.
Column 12, line 28, delete "filly" and insert --fully--.	See page 21, line 18 of Description of the Preferred Embodiments.
Column 14, line 53, delete "first" and insert --at least--.	See page 4 of AMENDMENT dated March 22, 2004.

We respectfully request that this Certificate of Correction be expeditiously issued since the errors reported herein were incurred through the fault of the United States Patent and Trademark Office.

Attached hereto, in duplicate, is Form PTO-1050, with at least one copy being suitable for printing.

A duplicate of this document is attached.

Respectfully submitted,

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MODULAR GRAFTING SYSTEM AND METHOD

This application is based on and claims the benefit of Provisional Application Serial No. 60/187,941, filed March 3, 2000.

BACKGROUND OF THE INVENTION

The present invention relates to the treatment or repair of vasculature and more particularly, to delivering a graft device within a blood vessel to address vascular disease.

In recent years, there have been developments in the treatment or repair of the vasculature of humans or other living animals. These developments have been applied to various areas of vasculature to treat a number of conditions such as vessel weakening or narrowing due to disease. The methods developed have involved minimizing the invasive nature of repair so that patient morbidity and mortality can be reduced. The period of recovery has also been reduced with such advances.

Some people are prone to degeneration and dilatation of the aorta, leading to rupture and death from bleeding. A recently-developed method of arterial reconstruction involves the attachment of a tubular conduit (graft) to the non-dilated arteries above and below the degenerated segment using stents; hence the name "stent-graft" for the prosthesis. The lumen of the arterial tree is used as a conduit to the aorta; hence the name "endovascular aneurysm repair" for the procedure.

The procedure is relatively simple when the degenerated segment is without significant branches. The stent-graft needs only one lumen with an orifice at each end. But the procedure is much more complicated when the degenerated segment of the aorta contains branches, because the stent-graft also needs to branch and these branches need to be placed along multiple lines of insertion. The most common, and simplest, example is reconstruction of the aortic bifurcation. This technical hurdle was crossed

components of the graft device of the present invention as well as a series of guidewires which provide a path taken by components of the delivery catheter system.

It is contemplated that a branched stent-graft of the present invention be constructed in-situ from multiple components, a main or primary stent-graft with multiple short branches and several branch extensions. Variations in arterial anatomy are accommodated intraoperatively through the independent selection of components as indicated by intraoperative measurements.

In one aspect, the device does not attempt to mimic native anatomy. For example, the widest portion of the primary stent-graft is attached (usually with a stent or an anchoring device) to the proximal aorta. All branches of the primary stent-graft originate at a level proximal to the branches of the aorta. The variable gap between branches of the stent-graft and branches of the aorta is accommodated by variation in the length of the extensions. Thus, several extensions run next to one another through the proximal aortic segment. This is possible because the central section of the primary stent-graft is sized to be much smaller than the native aorta in the region of the aortic branches. The space around the central section also allows for blood flow from the stent-graft branches to the aortic branches and continuing perfusion of the vital organs while extensions are added one by one. A distal aortic seal is established through a slightly wider segment. Alternatively, additional components can be added with their own branches to permit extension into other aortic branches, such as the iliac arteries.

The extensions can be fully-stented (lined from one end to the other with stents or some other means of support), yet flexible. As so configured, they maintain a stable position through a combination of stent support and anchoring or attachment mechanisms at both ends.

The two main sites requiring this kind of treatment are the aortic arch and the suprarenal aorta. The present invention also has applications in other complex anatomy including the iliac, hypogastric or femoral arteries. Although the principles are the same for such sites, differences in anatomy necessitate differences in basic technique.

52 and inferior 54 ends. That is, the midsection 56 has a circumference or radial dimension less than that of the superior 52 and inferior 54 ends, whereas the superior 52 and inferior 54 ends can have the same or different circumferences or radial dimensions. A transition section 74 is included medial each of the superior 52 and inferior 54 end portions whereat the circumference of the graft device narrows to that of the midsection 56. The circumference or radial dimension of the limbs 62, 64, 66 is generally less than that of the midsection section 56 and the limbs 62, 64, 66 can have equal or varied circumferences.

The main component can be fabricated by any convention means whether it be assembling separate pieces of graft material into a desired configuration or employing various weaving techniques to thereby have a one piece design. In one preferred approach of manufacture, several tubular pieces of standard vascular material can be attached to each other using suture. Further, the trunk (superior, inferior, and midsection portions) and limbs can embody woven polyester or PTFE folds or areas of double layers of material can be added as required to attach anchoring, grappling or support structures to the graft component.

In the present invention, it is contemplated that the superior end portion 52 be configured with an anchoring device 76 that operates to attach the main component 50 within vasculature. The anchoring device 76 can be placed or attached to an interior or an exterior of the main component 50 and can assume various forms. Additionally, the main component 50 can include support structures extending the entire length or a portion of the length of the main component 50 and various structures for mating with other graft components. The anchoring device can be within the length of the main graft or extend beyond the end of the graft as shown.

With reference to FIGS. 2 and 3, there is shown two forms of anchoring devices which may be used, although other forms can be employed as necessary. As shown in FIG. 2, a generally sinusoidal anchoring device 80 including a plurality of alternating apices 82 configured with torsion springs 84 and wall engaging members 86 attached

133, the fold 132 being held in place with clips or sutures 134 or any other equivalent means.

As shown in FIG. 7, the mating structure 140 can be defined by a framework 142 having opposing or alternating apices 144 and can be affixed to an interior (or exterior, as needed) circumference of a graft component 145 by sutures or equivalent structure 146. In one aspect, the apices 144 at a superior end 148 of the support structures 140 are intended to extend slightly radially inwardly so that a suitable engaging surface is provided. It is to be recognized that various forms of framework can be employed as such a mating structure provided the desired mating function is accomplished.

Moreover, the mating of two components of a modular graft can be accomplished through the frictional engagement of an outer circumference of one component with an inner circumference of another component. Such a frictional engagement can rely on surface irregularities or other more defined projections or can employ adhesives. It is also contemplated that structures such as that depicted in FIGS. 2 and 3 can be used to join two components. The wall engaging members 86, 98 of those structures 80, 90 are contemplated to lock the components together by penetrating the walls defining the components being joined. The expansion of the structures 80, 90 also ad in maintaining a sealed connection.

As shown in FIG. 8, a typical extension component 150 can embody a generally tubular shape. However, it is also contemplated that a limb component can also be bifurcated or trifurcated. The extension components can be made of any suitable conventional material. In one preferred embodiment, the extension components are made of PRFE.

A mating end 152 of a typical extension component is provided with some form of projection or grappling mechanism for engaging the corresponding mating structure of another graft component. In FIG. 8, there is shown one embodiment of an acceptable grappling or mating structure 154, although various other forms are

In order to determine the feasibility of endovascular repair of TAAA, CT and calibrated catheter angiography are employed. Measurements and the mapping of the target anatomy are taken and recorded. Graft components can then be assembled and sizes selected as necessary to be later used in a repair procedure.

It is contemplated that TAAA repair involves prolonged periods of magnified high resolution imaging, during which the field ranges back and forth from the neck to the groin of the patient, while the view ranges from full left lateral to full right lateral and every angle therebetween. The patient lies in a supine position under general endotracheal anesthesia. Arterial access is obtained through the femoro-brachial arteries by making oblique incisions, although longitudinal incisions can also be made. Heparin is given intravenously to maintain the activated clotting time at twice control from arterial puncture to arterial repair. In addition, heparinized saline is infused slowly through all individual sheaths used during the implant procedure and evoked potentials are continuously monitored. If there is a noticeable change, cerebral spinal fluid (CSF) is drained through a lumbar catheter and blood pressure can be supported pharmacologically to improve spinal perfusion.

With reference to FIGS. 14-22, various steps in treating or repairing a TAAA is described. As shown in FIG. 13, similar to the previously described graft devices, a main component 350 used in treating a TAAA embodies a superior end portion 352, an inferior end portion 354, and a midsection 356, as well as a plurality of limbs 362, 364, 365, 366. As before, the main component 350 is made from conventional fabric. An oblique anastomotic line joins the superior portion 352 to the limbs 362, 364, 365, 366 and inferior end portion 354. The limbs 362, 364, 365 and 366 are staggered longitudinally along the main component 350 an the midsection is tapered with respect to the superior end portion 352 to provide space for the limb. The inferior end portion 354 can have a much smaller diameter to provide space for mating with limb extensions.

Delivery of the main component 350 within the target site requires a sheath such as a large bore 20-24 French sheath. Any conventional delivery catheter so equipped can be employed. Such conventional catheters may further include an expandable or inflatable member for opening or implanting the support and anchoring devices attached to the main component 350. The delivery catheter is additionally contemplated to include structures or means for accomplishing relative longitudinal movement between the main component 300 and the delivery catheter in order to facilitate deployment and implantation. Conventional guidewires are also contemplated for providing a path taken by any of the delivery catheters used to deploy components of the graft device of the present invention.

In operation, the main component 350 is advanced to a desired level within the thoracic aorta 400 and rotated to align the limbs 362, 364, 365 and 366 with their corresponding branch arteries. A trans-brachial catheter (not shown) can be used for angiographic localization of the branch arteries. The goal is to position the terminal ends of the limbs 362, 364, 365, 366, 1-2 cm above the corresponding branch artery.

With specific reference to FIGS. 15-19, there is shown a preferred procedure for attaching or overlaying a limb extension 452 with a limb 362 of the main or first component 300. As described above, the limb extensions 452 can be fully supported with the devices shown in FIGS. 2-5, 15-22 about an interior or exterior of a particular limb extension 452. The limb extensions are also equipped with grappling or corresponding mating structures (See FIG. 7, for example) configured to engage structures or devices affixed to the limbs 362, 364, 365, 366.

Limb extensions 452 are contemplated to be inserted through a surgically exposed brachial artery, right or left, depending upon the aortic arch anatomy. In theory, right-side access carries a greater risk of stroke, but it sometimes provides a less tortuous route to the descending thoracic aorta 400. As shown in FIG. 15, a guiding catheter 500 is inserted from the brachial artery to the proximal descending thoracic aorta 400. This helps guide the catheter 500 through the aortic arch and minimizes the

terminating with one of the at least four apertures and being attachable to one of the plurality of extension components.

Claims 17-26 (canceled)

Claim 27 (previously presented): The system of claim 1, further comprising a plurality of guidewires, each of the guidewires configured to be routed through an interior of the main component and out one of the at least four apertures to thereby provide a path for connecting the plurality of extension components to the main component.

Claims 28-42 (canceled)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

(Also Form PTO 1050)

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DATED : November 9, 2004

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